JUL 19 2007

K071292

Section 13 510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: 04. May 2007
Company / Institution name: **RICHARD WOLF MEDICAL INSTRUMENTS CORP.**			FDA establishment registration number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913 1113
Street address: 353 Corporate Woods Parkway			FAX number (include area code): (847) 913 0924
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP / Postal Code: IL 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			
Product Information:			
Trade name: View MD Office System		Model number: 41066.5540	
Common name: Light Source / Camera / Monitor		Classification name: Light Source	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1. K010033	1. Light Projector 4251.007 and Endocam Light 5551.107 with Camera Heads 5551.961 (NTSC) and 5551.901 (PAL)	1. Richard Wolf
2. K022490	2. KSEA Medi Pack	2. Karl Storz
3. Pre-enactment	3. Light source 4008, 4046, 4246	3. Richard Wolf
4. K950502	4. CCD Endocam Office 5501	4. Richard Wolf

1.0 Description

The View MD Office System is a 50 watt light source, 1 CCD camera, and LCD Monitor with image capture combined into a compact unit.

2.0 Intended Use

The View MD Office System is designed to deliver illumination, provide camera use, and display and store images obtained during endoscopic surgical or diagnostic procedures.

3.0 Technological Characteristics

There are no new technological characteristics when the sum of the separate components are compared to the combination device with the exception of the ability to store images on a USB Memory Stick.

4.0 Substantial Equivalence

The View MD Office System is substantially equivalent to separated devices currently sold by Richard Wolf , as well as, the Medi Pack device (K022490) sold by Karl Storz.

5.0 Performance Data

The View MD Office System has been tested to conform to IEC 60601-1 and IEC 61000-3-2 / -3, 61000-4-2 / -3 / -4 / -5 / -6 / -8 / -11.

6.0 Clinical Tests

No clinical test were performed.

7.0 Conclusions Drawn

The device is designed and tested to assure safety and effectiveness when used according to the instructions for use.

By: Robert L. Casarsa Date: May 4, 2007

Robert L. Casarsa

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2007

Richard Wolf Medical Instruments Corp.
% Mr. Robert L. Casarsa
Quality Assurance Manager
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061-3110

Re: K071292
Trade/Device Name: "View MD Office System" 41066.5540
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: May 4, 2007
Received: May 8, 2007

Dear Mr. Casarsa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5 Indications for Use

510(k) Number (if known): K071292

Device Name: "View MD Office System" 41066.5540

Indications for Use: The "The View MD Office System" is designed to deliver illumination, provide camera use, and display and store medical images obtained during endoscopic surgical or diagnostic procedures

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ANOTHER PAGE IF NEEDED

Concurrence of CDHR office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071292

Prescription use ✓ and / or Over-The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart D)